Australian Government

Patent Office
Canberra

I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003906787 for a patent by COCHLEAR LIMITED as filed on 08 December 2003.

COMMONWEALTH OF AUSTRALIA
AUSTRALIA
PATENT OFFICE

WITNESS my hand this
Twenty-third day of December 2004

JANENE PEISKER
TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

An electrode array

The invention is described in the following statement:

Field of the Invention

The present invention relates generally to the field of forming miniature wiring and connector systems for electrical products. More specifically, the present invention relates to a method of forming electrical contacts with wiring and connector systems, electrode arrays, such as arrays for sensors, including biosensors, and implantable devices, such as an implantable recording or stimulating electrodes or pads for use in the body.

Background of the Invention

In many electrical devices, particularly those that are manufactured on a very small scale, the manufacture of the wiring and connector components is often a labour intensive and specialised craft. Ensuring that the wiring and connection of the various components of the systems occurs correctly is often the most expensive and labour intensive aspect of the manufacturing process, resulting in large costs associated with the time taken to manufacture the device which is often passed on to the ultimate consumer. This is also the case when such devices need to be specifically hand-made to a specification as often the availability of the device is dependent upon the time taken to manufacture the device, with the time taken being difficult or impossible to expedite.

This is particularly the case in the field of medical implants and electrical devices that are implanted in the body to perform a specific task. Such devices may include: stimulating devices such as pacemakers, cochlear implants, FES stimulators, recording devices such as neural activity sensors and the like, implantable cables which may be used to connect implantable devices to other implantable devices or stimulating/sensing devices, diagnostic devices capable of carrying out in-vivo analysis of body parameters, and other types of implantable devices not yet contemplated. In such devices, the size needs to be minimised to ensure that they are minimally invasive upon implantation. As a result, in such instances, the electronic wiring and connections need also to be relatively very small. As such, manufacturing such devices to ensure that they are reliable and sturdy is a specialised art, and requires much time and expense.

As a result of the need to increase the miniaturisation of such devices, a wide range of techniques have been developed to create patterned components which would be too difficult or impossible to create by hand design and satisfy the high volume supply required. Techniques such as electroforming, vacuum deposition (sputtering, evaporation), and chemical vapour deposition are just some of the known ways to produce patterned electrically conductive features on insulating surfaces on a micron scale. The problem with such methods however, has been that the metallic films produced by these techniques have been shown to have properties that are different from the corresponding properties of the bulk materials used. This results in the desired materials functioning differently from their intended purpose, and in the particular case of platinum, thin films have tended to crack and exhibit large impedance as well as a high degree of delamination.

In the manufacture of such devices, the bulk material is chosen based on the properties it exhibits. In the case of implantable electrical components, platinum has been found to exhibit particularly useful properties for such an application, namely good conductivity and inertness. With this being understood, it is beneficial in the manufacture of such devices for the bulk material to exhibit the same properties, especially physical properties, after manufacture as it did prior to manufacture, as discussed above. Variations in these properties can have a bearing on the functionality of the device, which, particularly in medical implanted devices, is highly undesirable. As mentioned, platinum films tend to crack and delaminate, hence delivering high impedance which impairs the functionality of the device. The use of thin film technology has been shown to work for a number of materials such as copper, gold and nickel, however none of these materials are suitable for active implantable devices.

Because of these problems, medical implants, such as cochlear implants, are still manufactured using labour intensive manual procedures.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing an electrode assembly with an array of electrodes or stimulating pads, each electrode or pad being arranged and constructed to deliver a stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode or pad stimulate the nerves disposed on the modiolus of the

cochlea. As the size of the cochlea is very small and the electrode assembly needs to be flexible enough to be inserted into the cochlea, the dimensions of the electrode assembly are such that do not allow for traditional manufacturing techniques.

For this reason, the intracochlear electrode array has generally been formed in a manual process. Under a microscope, a plurality (eg. 22) of electrically conductive platinum rings are positioned in a linear array and then separately welded to a respective parylene coated Pt/Ir electrical conductive wire. Typically, each platinum ring has an outside diameter ranging between 0.6 mm to 0.65 mm. After welding, each ring is collapsed to form a U-shaped electrode.

This process can lead to small variations in the locations of the electrodes or pads and wiring from one manufactured array to the next with consequent small variations in the overall mechanical properties of the array once a resiliently flexible carrier member is moulded about the array. Each of the wires must be identified, tested and then connected to a receiver/stimulator unit. In order to ensure system integrity, each of the wires must also be insulated from the others so that unwanted interaction between different electrical components is eliminated.

While the above method has proven very successful, it is labour intensive and hence a relatively expensive process. With implanted devices and miniaturisation becoming more common, there is an increasing need to provide electronic wiring and electronic connections in such systems that are both simple and reliable. The present invention is directed to a method of forming such wiring and connections that addresses at least some of the problems with prior art processes.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

In a first aspect, the present invention is a method of forming a device comprised of a predetermined pattern of at least two relatively electrically conductive regions, the method comprising the steps of:

(a) working a sheet of electrically conductive material to remove predetermined portions therefrom to form said two or more discrete relatively conducting regions;

(b) connecting at least one electrically conducting wire to at least two of said at least two or more relatively conducting regions; and

(c) connecting a portion of each wire located distal said conducting regions to a common sacrificial member.

In this aspect, the steps can be performed in the order set out above. It will be appreciated that at least some of the steps could be performed in other orders or simultaneously. For example, step (c) could be performed prior to or at the same time as step (b) or step (a).

In this aspect, the step of working the sheet (i.e. step (a)) can include a step of punching portions out of the sheet of electrically conductive material. In this embodiment, portions of the sheet are removed and separated from the sheet.

Yet further, the step of working the sheet can include a step of slicing or cutting the sheet of electrically conductive material.

In yet another embodiment, the step of working the sheet can comprise a process of using electrical discharge machining (EDM), which is also known as spark erosion, to remove unwanted portions of the sheet as is described in the present applicant's International Publication No WO 02/089907, the contents of which are incorporated herein by reference.

In a further embodiment, the step of connecting the wires (i.e. step (b)) can comprise a step of welding each wire to a respective relatively conducting region. In

one embodiment, a distal end of the wire is welded to the conducting region. It will be appreciated that the connection could be made at a location away from the end of the wire. In this case, however, it is envisaged that the wire would then be trimmed.

In yet another embodiment, the step of connecting a proximal portion of the wire to a sacrificial member (i.e. step (c)) can comprise a step of welding each wire to the sacrificial member. In one embodiment, a proximal end of the wire is welded to the sacrificial member. It will be appreciated that the connection could be made at a location away from the proximal end of the wire. In this case, however, it is envisaged that the wire would then be trimmed at the location of the weld.

In one embodiment, each of the wires can be individually welded to their respective conductive region and the sacrificial member. In another embodiment, two or more wires can be welded simultaneously, at one or both locations. In another embodiment, all of the wires can be welded simultaneously, at one or both locations. In a further embodiment, the welding can be performed manually. In a preferred embodiment, an automatic welding machine can be used to weld the wires to the conductive regions and the sacrificial member.

It is preferred that the wires are welded to the sacrificial member in a manner that allows ready identification as to which conductive region the wire is extending from. For example, the proximal ends of the wires can be aligned transversely along the sacrificial member. For example, where there are a plurality of conductive regions disposed in a longitudinal array and the same number of wires extending therefrom, the wire extending from the region that is most distal the sacrificial member can be at one end of the member, the wire from the next most distal region beside it, and so on until each of the wires are electrically connected, such as by welding, to the sacrificial member.

This ordering of the connection of the wires to the sacrificial member results in there being no need to retest which wire is connected to which conductive region at a later date in a manufacturing process that uses the device according to the first aspect. Instead, it is possible by noting the location of the weld of the wire to the sacrificial member to determine which conductive region that wire is extending from.

The wire can be formed from a biocompatible electrically conductive material. In a preferred embodiment, the wire is formed from a suitable metal or metal alloy. In one embodiment, the wire can be formed from platinum or platinum/iridium alloy. In one embodiment, the wire is circular in cross-section. Other shapes of wire are envisaged, including wires that are oval in cross-section, or are foil-like having a width greater than its thickness.

In one embodiment, the wire can be coated with an electrically insulating material, such as a polymer material. In one embodiment, the electrical connection formed between the wire and the conductive region and/or sacrificial member, such as the formation of a weld, can be performed through the insulating layer.

In another embodiment, the wire can be uncoated when electrically connected to the conductive region and/or sacrificial member. In this case, it is envisaged that the device formed by the method according to the first aspect would undergo a coating step where at least the wires are encapsulated in an electrically conducting material.

For example, the device could be passed through a parylene coater so as to coat at least parts of the device with a suitable layer of parylene. In this case, it is envisaged that the electrically conductive regions would be masked to prevent their coating with parylene.

In one embodiment, the method can further include the step of encapsulating the device in an electrically insulating material. This material is further also preferably biocompatible and resiliently flexible. One example of a possible encapsulating material is silicone. The result is preferably a plurality of separate electrically independent conductive portions having a layer of silicone encapsulated on one side thereof. If desired, the formed device can undergo further processing, including washing and drying, to render it suitable for implantation.

In one embodiment, the sacrificial member is in the form of a plate. The sacrificial member as its name implies is adapted to be sacrificed when the device made by the method according to the first aspect is ready to be utilised for the purpose for which it was manufactured. In one embodiment, the plate is preferably formed from a suitable metal to allow welding of the distal ends of the wires to the plate.

In a preferred embodiment, the device formed by the method according to the first aspect is preferably an electrode array for an electrode assembly. The method has potential advantages in providing a relatively efficient and inexpensive process of electrode assembly manufacture, particularly assembly of intracochlear electrode assemblies. The present invention further provides a method of forming an electrode array for an electrode assembly that preferably allows the manufacturing process to become automated or semi-automated so providing a desirable alternative to current manufacturing processes which require extensive labour input and increased manufacturing throughput.

In a preferred embodiment, the electrode array is for use as an implantable tissue-stimulating device. More preferably, the tissue-stimulating device is a cochlear electrode assembly, more preferably an intracochlear electrode assembly. In another embodiment, the electrode array could be used in a biosensor not necessarily related to an implanted device.

In this embodiment, the electrically conductive regions formed in step (a) comprise the plurality of stimulating pads or electrodes of the array. The wires are welded to these electrodes and extend therefrom to a sacrificial plate. The wires remain welded to the plate until such time as the array is required for the manufacturing process in which the wires are connected to a feedthrough device that provides electrical connection through the wall of an implantable component, such as a receiver/stimulator unit. In this regard, the wires can be cut away from the plate when connection needs to be made to the feedthrough. The plate can then be disposed of or re-used.

In one embodiment, the sheet of electrically conductive material worked in step (a) is a biocompatible material. In a preferred embodiment, the sheet is a metallic material. Still further, the metallic material is a sheet of platinum. In a further embodiment, the sheet can be annealed. In a further embodiment, each of the electrodes are formed from a single sheet of electrically conductive material, such as platinum. In a further embodiment, more than one array can be formed from a single sheet of platinum. In yet a further embodiment, the sheet could be a laminate of two or more layers (eg Pt & Ir), or could be an alloy.

The sheet preferably has a thickness between about 10 and 200 microns, more preferably between about 20 and 100 microns. The method preferably uses a sheet of platinum having a thickness of around 50 microns. Other suitable thicknesses can be envisaged. Each sheet can have dimensions of about 50mm x 250mm. The size of the sheet will though depend on the requirements of the tooling used to work the sheet. As such, sheets of different dimensions can be envisaged.

The wires are preferably linearly aligned for at least a majority, and preferably all, of their length extending away from the electrode array. In one embodiment, the wires can be disposed for at least a portion of their lengths in a parallel arrangement.

The sheet of conductive material can, before the working step, be a planar sheet. Sheets that already have folds or embossments formed therein prior to the working step of the present invention can, however, also be envisaged.

In one embodiment, the step of working the sheet can further comprise deforming at least a portion of the planar sheet in a third dimension. For example, once a plurality of planar conductive electrodes are at least partially formed, they can be placed in a concave moulding die in which they are deformed to adopt a curved configuration. In one embodiment, this step can occur prior to step (b). Where the electrodes have a curved configuration, the wires can be joined, such as by automatic welding, to the concave surfaces of the respective electrodes.

In one embodiment, the respective electrodes formed from a planar sheet can be substantially rectangular or rectangular. Other suitable shapes for the formed electrodes can, however, be envisaged. In one embodiment, the portions of the sheet removed from the sheet can be bone -shaped.

In producing an electrode array, it is firstly desirable to determine the configuration of the stimulating pads desired for the electrode array. Once the configuration is determined, the step of working the sheet can comprise working the sheet, such as by using a punch that is fabricated for use in the method or other technique as defined herein, so as to produce the desired electrode array configuration.

Various techniques for punching, cutting, and otherwise working the sheet are also described in International Patent Publication No. WO 02/089907 already referenced herein.

In one embodiment, two or more arrays formed using the method can be laminated together to form a single tissue stimulating electrode assembly. In one embodiment, the assembly can be formed from a first lamination having 7 electrodes, a second lamination having 8 electrodes and a third lamination having 8 electrodes, to form an electrode assembly having 23 electrodes. In the case of a cochlear electrode array, the formed array will preferably have 22 intracochlear electrodes and one extracochlear electrode. Such a lamination process preferably results in a linear array of the 22 electrodes. It will be appreciated that other combinations of layers and other numbers of electrodes in each layer could be utilised to form arrays of different lengths, up to around 100 electrodes.

It will be appreciated that it is generally important that the lead which is comprised of the wires extending from the array to the feedthrough is capable of a degree of flexibility to compensate for any movement between the stimulator and the electrodes, such as movement which may naturally occur due to body growth. In one embodiment, the method can comprise a still further step of winding the lead in a helical manner. In one embodiment, the winding can result in the lead having a helical portion. The winding can be such that the wires extend over the same longitudinal extent in the helical portion. Techniques for forming the winding are described in the present applicant's International Application No. PCT/AU03/01369, the contents of which are incorporated herein by reference.

According to a second aspect, the present invention is a device when formed by the method as defined herein comprising:

a predetermined pattern of at least two electrically conductive regions; and

at least one wire extending from each of the conductive regions to a common sacrificial member.

In one embodiment, the device is preferably an electrode array. The electrode array can be suitable for use in tissue-stimulating and sensor applications or otherwise as defined herein with reference to the first aspect of the invention.

According to a third aspect, the present invention is a method of making an implantable electrode array, the method comprising the steps of:

(a) supporting a sheet of electrically conductive biocompatible material;

(b) working the sheet to remove one or more first portions therefrom;

(c) connecting at least one electrically conducting wire to said punched sheet using an automatic welding machine; and

(d) working the sheet to remove one or more second portions therefrom to form two or more discrete relatively conducting regions.

Preferably, the sheet is no greater than around 200 microns thick.

Preferably, the working of the sheet in step (b) comprising punching the sheet.

Preferably, a portion of each wire is located distal said conducting regions to a common sacrificial member.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a flow chart depicting at least some of the steps of one embodiment of the method of forming an electrode array according to the present invention;

Figs. 2a and 2b are a plan and perspective view of an electrode array formed in a platinum sheet;

Fig. 3 depicts the electrode array of Fig. 2b following the welding of wires thereto;

Fig. 4 depicts the electrode array of Fig. 3 following a further working step; and

Fig. 5 depicts another embodiment of set of electrodes with wires that are welded thereto extending away therefrom.

Preferred Mode of Carrying out the Invention

Processes according to embodiments of the present invention for the manufacture of an electrode array are depicted in the drawings.

Current techniques for the manufacture of electrode arrays for cochlear implant systems are relatively highly labour intensive. This is in the main due to the intricate nature of the array and the very small dimensions of the array necessary to allow it to be inserted in the scala tympani of the human cochlea. Being an implantable device, the method of manufacture also needs to result in a biocompatible product that is not susceptible to damage from long-term placement in the body.

Fig. 1 is a flow chart of an example of some of the steps of a method according to the present invention, depicted generally as 40, for forming an electrode array that is suitable for use as a tissue-stimulating device within the human cochlea.

As depicted, the method 40 comprises a series of steps 41 to 44 which form the electrode array. In the depicted method 40, and with further reference to Fig 2a, a platinum sheet 23 is used as it is a biocompatible material and is a proven material for use in cochlear implants manufactured using traditional techniques. The sheet 23 is in the form of a foil and typically has a thickness of around 50 microns, although this can vary between about 10 and 200 microns.

In step 41 of the depicted method, the platinum sheet 23 is firstly supported in a holder. The method 40 further comprises a step 42 in which an electrode array pattern is formed in the supported platinum sheet 23. In this example, the following step 42 comprises removing portions of the platinum sheet 23 therefrom such that at least the desired pattern of the electrode array remains. In the example, step 42 comprises a process of using a punch to punch out unwanted portions of the sheet 23.

As depicted in Fig. 2a, the punch can firstly remove rectangular portions 28 of the sheet 23 leaving a plurality of portions that will become the electrodes 25 of the array after later removing the outer portions 23a of the sheet 23 along the dotted lines shown in Fig 2b. In the depicted embodiment, the electrodes 25 formed in the sheet 23 have a size of about 0.4 mm^2 – 0.5mm^2. While the electrodes 25 are depicted as rectangular in shape, it will be appreciated that the electrodes could be formed in

different shapes by using a punch to remove non-rectangular portions from the sheet. For example, the punch can be adapted to remove bone-shaped portions.

As depicted in Fig. 2b, the step 42 can further comprise a step of deforming the sheet 23 in a third dimension. In Fig. 2b, the electrodes 25 of the sheet have been deformed so as to adopt a curved configuration by being placed in a concave moulding die.

It will be appreciated that in step 42, those portions of the sheet 23 to be removed can be removed by other techniques, such as laser ablation, micro-knifing, milling, or electrode discharge machining to remove the unwanted portions 28 of the sheet 23.

The method 40 further comprises a step 43 of welding electrically conducting wires 26 to the concave faces of the electrodes 25 (see Fig. 3). The wire 26 can be coated with an electrically insulating material, such as a polymer material such as parylene. A small area of the insulating material is removed at the end of the wire prior to the welding step. This welding is performed by an automatic welding machine. In the depicted embodiment, the wires 26 are formed from platinum or a platinum/iridium alloy and are circular in cross-section. Other shapes of wire are envisaged, including wires that are oval in cross-section, or are foil-like having a width greater than its thickness.

The outer portions 23a of the sheet 23 serve to hold the sheet in the pattern formed during step 42 during subsequent processing steps.

During step 44, the sheet 23 is preferably trimmed to remove the remaining portions 23a of the sheet that are not comprising the desired electrode array 24 (see Fig. 4). In the depicted example, the sheet 23 is trimmed with a knife. In another embodiment, a punch and die can be used to cut the electrode array from the remaining portions of the original sheet 23.

Each of the electrodes 25, and the corresponding welded wires 26, are formed in a manner such that their position with respect to each other is predetermined and kept constant throughout the process and in the final product.

To maintain this, step 43 can include a step where the proximal ends 27 of each of the wires are welded to a sacrificial plate 31 (see Figs. 3 and 4). It will be appreciated that the connection to the plate 31 could be made at a location away from the proximal end 27 of the wire 26. In this case, however, it is envisaged that the wire 27 would then be trimmed at the location of the weld.

It will be appreciated that each of the wires 26 can be individually welded to their respective electrodes 25 and the sacrificial plate 31. It is, however, preferred that the wires 26 be welded at least substantially simultaneously, at one or both locations, by the automatic welding machine.

As depicted in Figs. 3 and 4, the proximal ends 27 of the wires 26 can be aligned transversely along the sacrificial plate 31. As such, when there are a plurality of electrodes 25 disposed in a longitudinal array and the same number of wires 26 extending therefrom, the wire 26 extending from the electrode 25 that is most distal the sacrificial plate 31 can be at, near or closer to one end of the plate 31, the wire 26 from the next most distal electrode 25 beside it, and so on until each of the wires 26 are electrically connected to the sacrificial plate 31.

This ordering of the connection of the wires 26 to the sacrificial plate 31 results in there being no need to retest which wire 26 is connected to which conductive electrode 25 at a later date in the manufacturing process. Instead, it is possible by noting the location of the weld of the wire 26 to the sacrificial plate 31 to determine which electrode 25 that wire 26 is extending from.

The sacrificial plate 31 as its name implies is adapted to be sacrificed when the electrode array is ready to be electrically connected to a feedthrough device that provides electrical connection through the wall of an implantable component, such as a receiver/stimulator unit of a cochlear implant. For example, the wires 26 can simply be cut from the plate 31 when the wires 26 are to be welded to the feedthrough.

It will be appreciated that a number of electrode sets with corresponding sacrificial plates as depicted in Figs. 3 and 4 could be formed and stacked or laminated together and appropriately encapsulated to form a single tissue stimulating electrode assembly. One example of such an assembly is depicted by Fig. 5. In this

embodiment, the electrodes 25 are, however, still planar despite the wires 26 having been welded thereto.

In the case where the electrodes are still planar and as is described in International Publication No WO 02/089907, once the stack is formed, the hitherto at least substantially planar electrodes 25 can then be deformed so as to at least partially extend in a third dimension. In one embodiment, each of the electrodes are curved out of the plane of the wires 26 for each set of electrodes. The curvature can be substantially semi-circular. A mandrel can be used to form the curvature in the electrodes.

Once the electrodes 25 have been deformed to have a substantially semi-circular curvature, each of the electrodes 25 can be further folded about a longitudinal axis of the array. This folding of the electrodes 25 serves to bend the electrodes around the wires 26 of the array. The electrodes are preferably folded together and define a lumen that extends through the array.

The lumen can act as a substance delivery means for delivering a bio-active substance to the implant site following implantation. Alternatively or additionally, the lumen can receive a stylet to assist in insertion and placement of the array in the cochlea.

Once the electrode array is complete, it is preferably encapsulated in a mould in a further layer of a biocompatible silicone material to form an electrode carrier member. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the carrier member. In this arrangement, the electrodes are preferably positioned in the mould so as to not be coated with the silicone.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this eighth day of December 2003

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

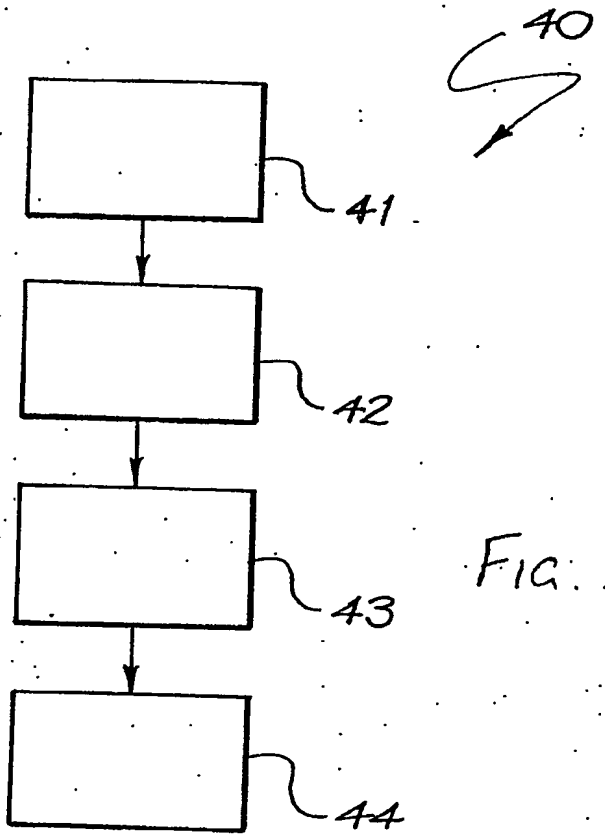

FIG. 1

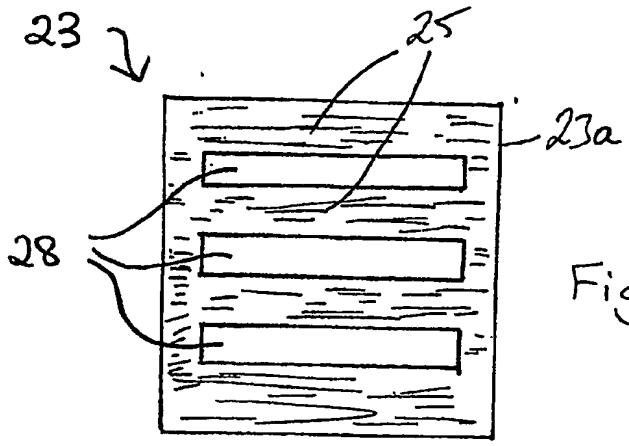

Fig. 2a

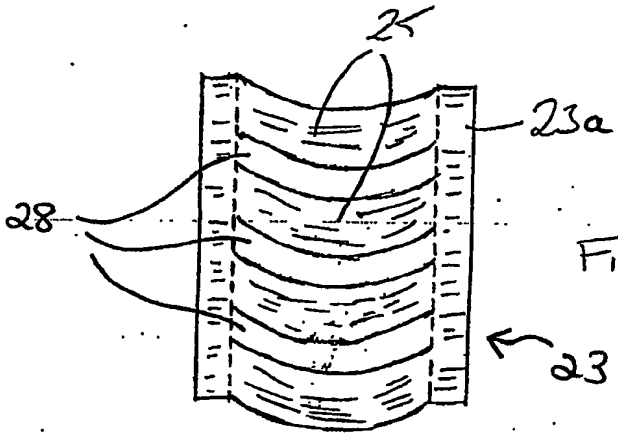

Fig. 2b

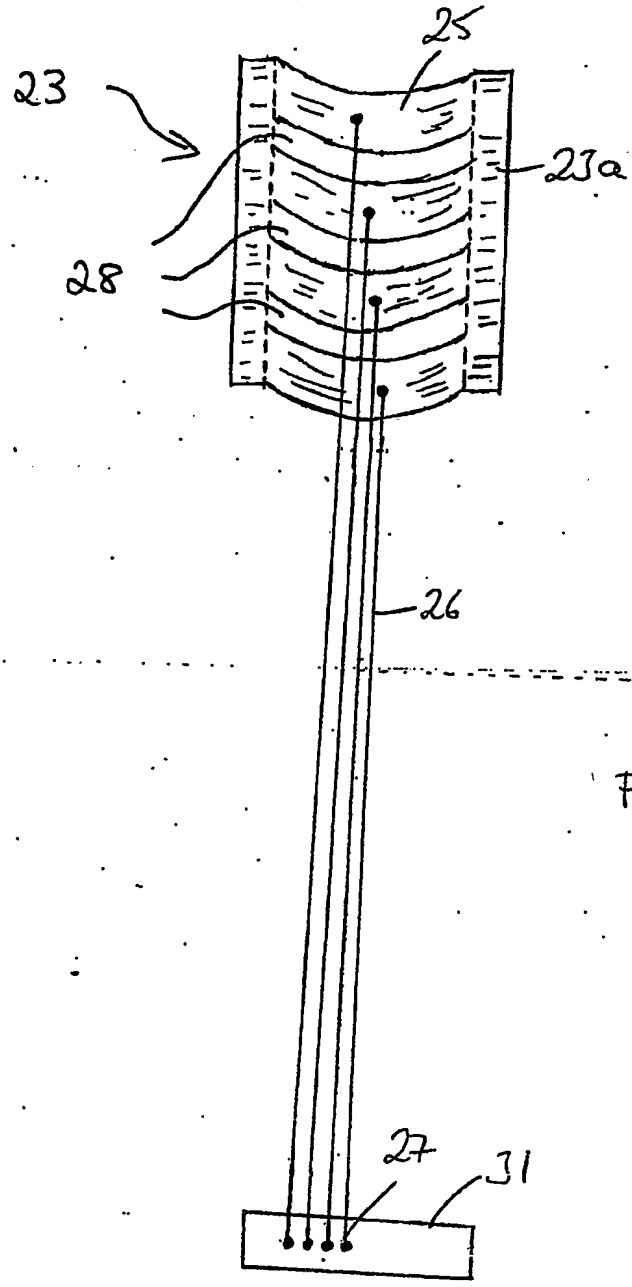

Fig. 3

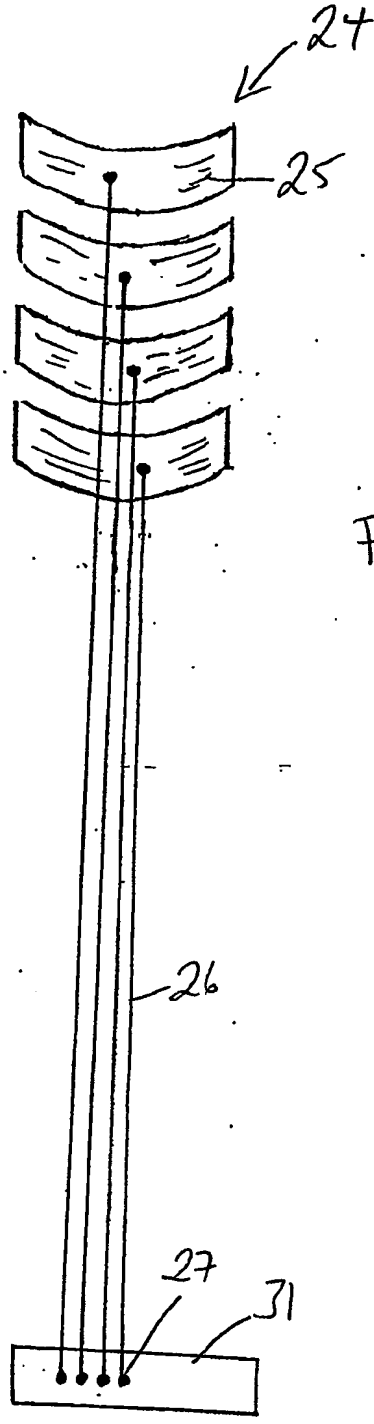

Fig. 4

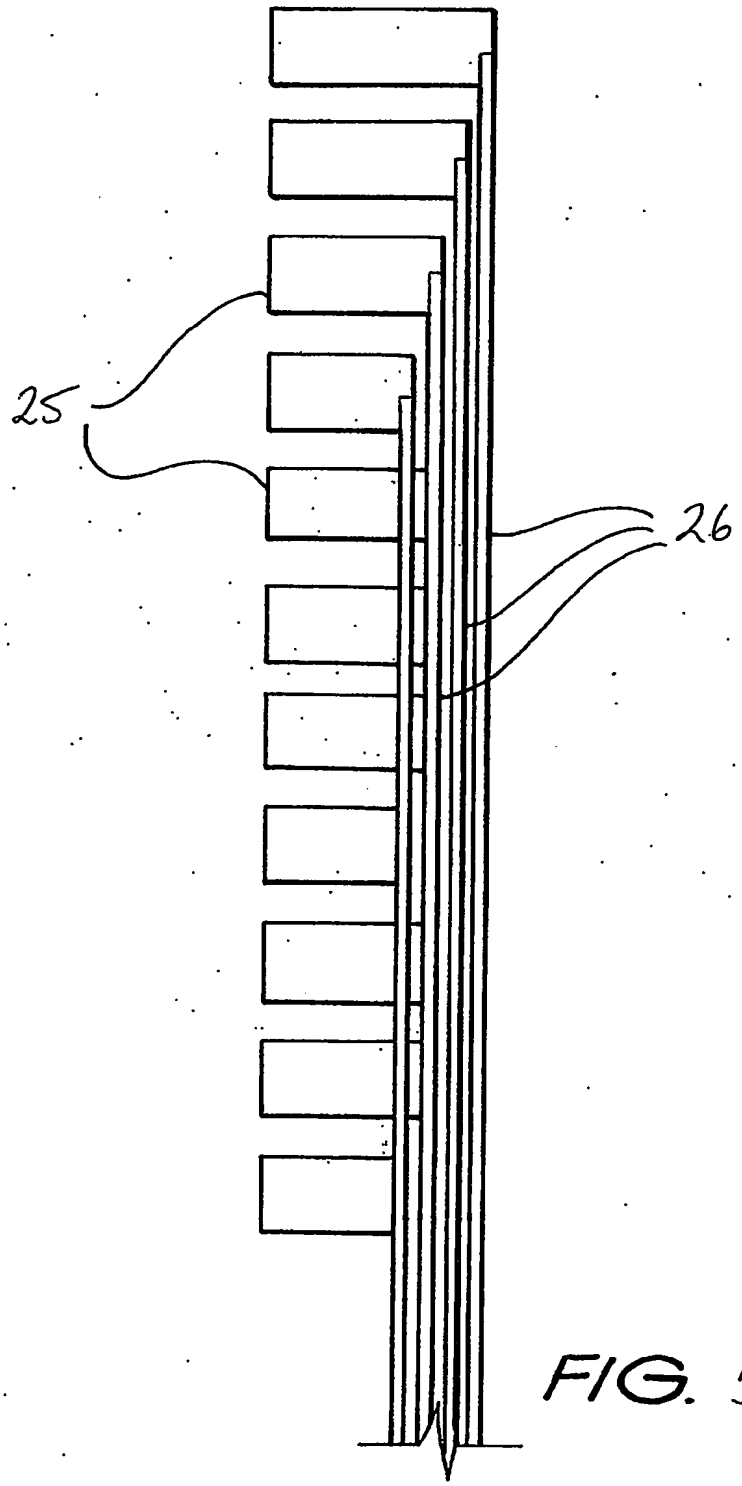

FIG. 5

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/AU04/001726

International filing date: 08 December 2004 (08.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: AU
Number: 2003906787
Filing date: 08 December 2003 (08.12.2003)

Date of receipt at the International Bureau: 11 January 2005 (11.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse